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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,979	03/07/2001	Masayuki Fukumura	4001-0003	8941
7590	06/08/2004		EXAMINER	
Mark R. Shanks REED SMITH LLP 1301 K Street, N.W. Suite 1100 East Tower Washington, DC 20005-3373			KATCHEVES, KONSTANTINA T	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 06/08/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/720,979	FUKUMURA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Konstantina Katcheves	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 16 July 2003.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-6,8-12 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-6, 8-10, 14-18 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8/28/03, 10/22/03
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

Claims 1-6, 8-12 and 14-18 are pending in the present application. Claims 1-6, 8-10 and 14-18 are currently under consideration. Claims 11 and 12 have been withdrawn. This Office action is in reply to the amendment and remarks, filed 16 July 2003.

***Response to Amendment***

The provisional rejection of claims 1-7 and 13-15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 9 of copending Application No. 09/070938 has been withdrawn in view of Applicant's arguments.

Claims 1-7 and 13-15 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 09/762641. Applicant's intention to file a terminal disclaimer upon allowance of the claimed invention is noted.

The amendment filed 16 July 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The temperature range of 38°C to 38.5°C is not supported by the specification. The specification prior to this amendment had what may or may not have been a temperature range, *i.e.* "38°C to 38°C". If this was a range, the upper limit

could not have been surmised. Applicant is required to cancel the new matter in the reply to this Office Action.

The objection to grammatical errors on page 19 of the specification are withdrawn based on the amendments filed.

Claims 1-6, 8-10 and 14-15 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-6, 8-10 and 13-15 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *in vivo* methods for gene therapy in rats and mice, does not reasonably provide enablement for *in vivo* methods in other organisms.

Claims 1-10 and 14-15 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention because it is unclear whether claim one is drawn to a method or inappropriately to a method and a product.

#### ***Response to Arguments***

Claims 1-6, 8-10 and 14-15 and new claims 16-18 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time

the application was filed, had possession of the claimed invention. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that the have amended the negative-sense RNA virus such that it belonging to the Paramyxoviridae family, argues that the disclosure teaches the structure of Sendai virus as containing six genes and argues that the structure is common in other paramyxoviruses as illustrated in Conzelmann et al. Given these reasons, Applicant argues "one skilled in the art would have readily expected that paramyxoviruses other than Sendai virus can be used in the instant invention."

First, this rejection is a written description rejection under 35 U.S.C. 112, first paragraph. The inquiry in these rejections is whether the invention was described in such a way so that one of skill in the art could reasonably conclude that Applicant had possession of the broad genus claimed. Applicant argues that the disclosure and art teach one of skill in the art to readily expect that other viruses can be used. This argument fails to teach that Applicant had possession of the claimed invention.

Even considering the amendment and the teaching of the art provided by Applicant, Applicant fails to have possession of the broad class of negative sense RNA viruses belonging to the Paramyxoviridae family. The genus of viruses and cells comprising such viruses embraced by these claims includes wild-type virus and modified, mutated or attenuated viruses. Applicant has not taught common structural features of this genus such that one of skill in the art would reasonably conclude he had possession of the invention.

Claims 1-6, 8-10 and 14-15 and new claims 16-18 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *in vivo* methods for gene therapy in rats and mice, does not reasonably provide enablement for *in vivo* methods in other organisms. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that none of the art cited relates specifically to negative-strand RNA viruses. Applicant acknowledges that these references discuss drawback associated with many different types of viruses. These references teach problems common to using viruses, in general, as a *in vivo* gene delivery vehicle. Therefore, the discussion from the prior art is relevant to the present discussion regarding enablement. Applicant also argues that Verma et al. conclude that the problems of gene therapy are not insurmountable and that gene therapy will become routine and that Crystal et al conclude that human gene transfer is feasible. Applicant cites the prophetic aspirations of those in the art of the success of human gene therapy as evidence that they are enabled for *in vivo* delivery of exogenous nucleic acids. Applicant has failed to provide evidence that human gene therapy is indeed predictable enough so that the practice of the present invention is not subject to undue experimentation. Moreover, with regard to Applicant's assertion that the Examples provided teach the requisite information to overcome the deficiencies in the art. Applicant's disclosure has been fully considered. Although Applicant does teach methods involving *in vivo* treatment of mice, it is clear from the Crystal et al., cited and discussed fully in the prior action, that one cannot extrapolated such animal data to human systems. The fact that human gene therapy is complex and unpredictable such that one of skill in the art would have to engage in an undue amount of experimentation is further supported by art on Applicant's IDS filed 22 October 2003. Wu et al. state that: "another obstacle in gene delivery for brain neurons

involves the infusion of vectors or plasmids into the cells in a functional, non-toxic manner.” Thus, given the evidence as a whole, one of skill in the art would be unable to make and use the full scope of the invention claimed.

Claims 1-6, 8-10 and 14-15 and new claims 16-18 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention because it is unclear whether claim one is drawn to a method or inappropriately to a method and a product.

Applicant’s amendment has failed to clarify the internal inconsistency present in the claim wherein the claim purports to deliver a nucleic acid yet does so by providing a negative sense RNA viral vector or cells comprising said vector. Is the nerve cell of the claim contacted with the nucleic acid of the claim at all, or merely with the viral vector?

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves  
Examiner  
Art Unit 1636



JAMES KETTER  
PRIMARY EXAMINER